EXHIBIT K

In the Matter Of:

NEW ENGLAND COMPOUNDING PHARMACY INC. PRODUCTS LIABILITY

VIDEOTAPED DEPOSITION OF FRANCIS MCATEER

June 03, 2015

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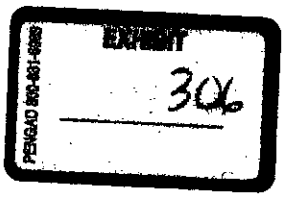

Inspections, Compliance, Enforcement, and Criminal Investigations

New England Compounding Center 04-Dec-06

Department of Health and Human Services

Public Health Service
Food and Drug Administration

New England District
One Montvale Avenue
Stoneham, Massachusetts
02180
(781) 596-7700
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WARNING LETTER

NWE-06-07W
VIA FEDERAL EXPRESS

December 4, 2006

Barry J. Cadden, Director of Pharmacy and Owner
New England Compounding Center
697 Waverly Street
Framingham, MA 01702

Dear Mr. Cadden:

On September 23, 2004, investigators from the U.S. Food and Drug Administration (FDA) and the Massachusetts Board of Pharmacy inspected your firm, located at 697 Waverly Street, Framingham, Massachusetts. On January 19, 2005, the inspection was completed. This inspection revealed that your firm compounds human prescription drugs in various dosage forms and strengths.

We acknowledge the receipt of your October 1, 2004, letter addressed to FDA's New England District Office, concerning questions presented during the referenced inspection.

FDA's position is that the Federal Food, Drug, and Cosmetic Act (FDCA) establishes agency jurisdiction over "new drugs," including compounded drugs. FDA's view that compounded drugs are "new drugs" withi the meaning of 21 U.S.C. § 321(p), because they are not "generally recognized, among experts . . . as safe and effective," is supported by substantial judicial authority. See Weinberger v. Hynson, Westcott & Dunning, 412 U.S. 609, 619, 629-30 (1973) (explaining the definition of "new drug"); Prof'ls & Patients for Customized Care v. Shalala, 56 F.3d 592, 593 n.3 (5th Cir. 1995) (the FDCA does not expressly exempt pharmacies or compounded drugs from its new drug provisions); In the Matter of Establishment Inspectio of: Wedgewood Village Pharmacy, 270 F. Supp. 2d 525, 543-44 (D.N.J. 2003), aff'd, Wedgewood Village Pharmacy v. United States, 421 F.3d 263, 269 (3d Cir. 2005) ("The FDCA contains provisions with explicit exemptions from the new drug . . . provisions. Neither pharmacies nor compounded drugs are expressly exempted."). FDA maintains that, because they are "new drugs" under the FDCA, compounded drugs may not be introduced into interstate commerce without FDA approval.

The drugs that pharmacists compound are not FDA-approved and lack an FDA finding of safety and

efficacy. However, FDA has long recognized the important public health function served by traditional pharmacy compounding. FDA regards traditional compounding as the extemporaneous combining, mixing, or altering of ingredients by a pharmacist in response to a physician's prescription to create a medication tailored to the specialized needs of an individual patient . See Thompson v. Western States Medical Center, 535 U.S. 357, 360-61 (2002). Traditional compounding typically is used to prepare medications that are not available commercially, such as a drug for a patient who is allergic to an ingredient in a mass-produced product, or diluted dosages for children.

Through the exercise of enforcement discretion, FDA historically has not taken enforcement actions against pharmacies engaged in traditional pharmacy compounding. Rather, FDA has directed its enforcement resources against establishments whose activities raise the kinds of concerns normally associated with a drug manufacturer and whose compounding practices result in significant violations of the new drug, adulteration, or misbranding provisions of the FDCA.

FDA's current enforcement policy with respect to pharmacy compounding is articulated in Compliance Policy Guide (CPG), section 460.200 ["Pharmacy Compounding"], issued by FDA on May 29, 2002 (see Notice of Availability, 67 Fed. Reg. 39,409 (June 7, 2002)).[1] The CPG identifies factors that the Agency considers in deciding whether to initiate enforcement action with respect to compounding. These factors help differentiate the traditional practice of pharmacy compounding from the manufacture of unapproved new drugs. They further address compounding practices that result in significant violations of the new drug, adulteration, or misbranding provisions of the FDCA. These factors include considering whether a firm compounds drugs that are copies or essentially copies of commercially available FDA-approved drug products without an FDA sanctioned investigational new drug application (IND). The factors in the CPG are not intended to be exhaustive and other factors may also be appropriate for consideration.

1. Copies of Commercially Available Druo Products;

It has come to our attention that you are compounding trypan blue ophthalmic products. During the inspection at your firm, you advised an investigator from FDA's New England District Office that the trypa blue products that your firm compounds are devices. FDA classifies trypan blue products as drugs, not devices. Further, on December 16, 2004, trypan blue ophthalmic solution was approved by FDA and it is commercially available. As stated in the CPG, FDA will not exercise its enforcement discretion for the compounding of copies of commercially available FDA-approved products, including this one.

We have also learned that your firm may be compounding 20% aminolevulinic acid solution (ALA). Please note that there is a commercially available, FDA-approved aminolevulinic acid solution 20% . Like compounded trypan blue, FDA regards compounded 20% aminolevulinic acid solution as a copy of commercially available drug.

Although Section 503A of the FDCA (21 U.S.C. § 353a) addresses pharmacy compounding, this provision was invalidated by the Supreme Court's ruling in Thompson v. Western States Medical Center, 535 U.S. 357 (2002), that Section 503A included unconstitutional restrictions on commercial speech . And those restrictions could not be severed from the rest of 503A. In Thompson v. Western States Medical Center, 535 U.S. 357 (20020), the Supreme Court affirmed the Ninth Circuit ruling that the provisions in question violated the First Amendment.

FDA does not sanction the compounding of copies of FDA-approved, commercially available drugs and the agency will not exercise its enforcement discretion regarding the trypan blue and ALA products compounded by your firm.

All products compounded by your firm containing trypan blue or ALA are drugs within the meaning of section 201(g) of the FDCA (21 U.S.C. § 321(g)). These products are misbranded under section 502(f)(1) of the FDCA (21 U.S.C. § 352(f)(1)) in that their labeling fails to bear adequate directions for their use. They are not exempt from this requirement under 21 CFR § 201 .115 because they are new drugs within the meaning of section 201(p) of the FDCA and they lack approved applications filed pursuant to section 505 of the FDCA (21 U.S.C. § 355).

2. Anesthetic Drug Products

Equally serious, your firm's promotional materials reveal that it offers to compound "Extra Strength Triple Anesthetic Cream" which contains 20% benzocaine, 6% lidocaine, and 4% tetracaine. Like a manufacturer you have developed a standardized anesthetic drug product that you sell under the name "Extra Strength Triple Anesthetic cream," Further, you generate sales by giving physicians "courtesy prescriptions" (i.e., free samples). These actions are not consistent with the traditional practice of pharmacy compounding, in which pharmacists extemporaneously compound reasonable quantities of drugs upon receipt of valid

prescriptions from licensed practitioners to meet the unique medical needs of individual patients.

Moreover, the agency is concerned with the public health risks associated with the compounding of "Extra Strength Triple Anesthetic Cream." There have been at least two nonfatal reactions and two deaths attributed to the use of compounded topical local anesthetic creams containing high doses of local anesthetics. Local anesthetics, like "Extra Strength Triple Anesthetic Cream," may be toxic at high dosages, and this toxicity can be additive. Further, there is a narrow difference between the optimal therapeutic dose of these products and the doses at which they become toxic, i.e. they have low therapeutic index.

Adverse events consistent with high systemic exposures to these products include seizures and cardiac arrhythmias. Specifically, risk of systemic adverse events from tetracaine products includes (1) a systemic allergic response to p-aminobenzoic acid (PABA) which, at worst, could lead to cardiac arrest; or (2) excessive systemic absorption following repetitive or extensive application, especially for a 4%a product, which could ultimately lead to convulsions. Tetracaine is associated with a higher incidence of allergic reactions than other anesthetics, such as lidocaine. The risk of systemic toxicity is greatest in small children and in patients with preexisting heart disease. Factors that may increase systemic exposur are time and surface area of the exposure, particularly when the area of application is covered by an occlusive dressing. Benzocaine has an additional toxicity not seen with (idocaine, methemoglobinemia, an acquired decrease in the oxygen-carrying capacity of the red blood cells. Further, patients with severe hepatic disease are at greater risk of developing toxic plasma concentrations of local anesthetics because of their inability to metabolize them.

The Extra Strength Triple Anesthetic Cream compounded by your firm is a drug within the meaning of section 201(g) of the FDCA (21 U.S.C. § 321(g)). This product is misbranded under section 502(f)(1) of th FDCA (21 U.S.C. § 352(f)(1)) in that its labeling fails to bear adequate directions for its use. It is not exempt from this requirement under 21 CFR § 201.115, because it is a new drug within the meaning of section 201(p) of the FDCA that lacks an approved application filed pursuant to section 505 of the FDCA (21 U.S.C. § 355).

Depending on its labeling, this product may also violate section 502(a) of the FDCA (21 U.S.C. § 352(a)). A drug or device is misbranded under section 502(a) if its labeling is false and misleading in any particula (e.g., if the labeling for your local anesthetic products fails to reveal the consequences that may result from the use of the product as a local anesthetic).

3. Repackaging:

Additionally, we are in receipt of a complaint alleging that you are repackaging the approved injectable drug, Avastin, into syringes for subsequent promotion and sale to health professionals . Avastin is unpreserved and is packaged and labeled in 4 and 16 ml single-use glass vials. The labeled precautions include "discard any unused portion left in a vial . . . ." Each step in the manufacture and processing of a new drug or antibiotic, from handling of raw ingredients to final packaging, must be approved by FDA, whether carried out by the original manufacturer or by some subsequent handler or repacker of the product. Pharmacists are not exempt from these statutory requirements. Generally, the agency regards mixing, packaging, and other manipulations of approved drugs by licensed pharmacists, consistent with the approved labeling of the product, as an approved use of the product if conducted within the practice o pharmacy, i.e., filling prescriptions for identified patients. However, processing and repacking (including repackaging) of approved drugs is beyond the practice of pharmacy and is thus subject to the Act's premarket approval requirements.

The agency has an established policy, articulated in Compliance Policy Guide Sec. 446.100, Regulatory Action Regarding Approved New Drugs and Antibiotic Drug Products Subjected to Additional Processing or other Manipulations (CPG 7132c.06) (copy enclosed), concerning the manipulation of approved sterile drug products outside the scope of the FDA-approval. FDA is particularly concerned about the manipulation of sterile products when a sterile container is opened or otherwise entered to conduct manipulations. The moment a sterile container is opened and manipulated, a quality standard (sterility) is destroyed and previous studies supporting the standard are compromised and are no longer valid. We are especially concerned with the potential microbial contamination associated with splitting Avastin - a single-use, preservative-free, vial -- into multiple doses. When used intravitreaily, microbes could cause endophthalmitis, which has a high probability for significant vision loss. The absence of control over storage, and delays before use after repackaging, only exacerbate these concerns.

Avastin is approved for use in the treatment of colorectal cancers. The text of your alleged promotional material offers this drug to ophthalmologists . Avastin has no approved indications for use in the eye. As

such, your firm is distributing an unapproved new drug in violation of section 505 of the FDCA. Because the product lacks adequate labeling for its intended use (see 21 CFR § 201.128) your firm is also distributing a misbranded drug in violation of section 502(f)(1) of the FDCA (21 U.S.C. § 352(f)(1)). Also, please note that, under section 301(a) of the FDCA (21 U.S.C. § 331(a)), the introduction or delivery for introduction into interstate commerce of any drug that is misbranded is prohibited.

Under section 301(d) of the FDCA (21 U.S.C. § 331(d)), the introduction or delivery for introduction into interstate commerce of a new drug that has not been approved under section 505 is also prohibited.

Further, we have been informed that, although your firm advises physicians that a prescription for an individually identified patient is necessary to receive compounded drugs, your firm has reportedly also told physicians' offices that using a staff member's name on the prescription would suffice. Drugs compounded in this manner are not compounded consistent with the CPG, and FDA will not exercise its enforcement discretion regarding those drugs.

The above violations are not intended to be an all-inclusive list of deficiencies. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in additional regulatory action without further notice, including seizure or injunction against you and your firm. Federal agencies are routinely advised of the issuance of warning letters so that they may take this information into account when considering the award of government contracts.

Please notify this office in writing within 15 working days of receipt of this letter of any steps that you wil take to correct the noted violations, including an explanation of the steps taken to prevent the recurrence of similar violatJons. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time within which the correction will be complete.

You should address your reply to this letter to the U.S. Food and Drug Administration, New England District Office, One Montvale Ave., 411 Floor, Stoneham, MA 02180, Attn: Ann Simoneau, Compliance Officer. If you have any further questions, please feel free to contact Ms. Simoneau at (781) 596-7732.

Sincerely,

/s/

Gail Costello
Disrict Director
New England District Office

Page Last Updated: 07/08/2009
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

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OUTSOURCING STERILE PRODUCTS PREPARATION

CONTRACTOR ASSESSMENT TOOL

ASHP Foundation™

Developed with support from PharMEDium Services, LLC.

Principles for Use

- When outsourcing sterile products preparation services, every hospital/health system-based department of pharmacy should take a comprehensive and organized approach to vendor selection.
- Departments of pharmacy are strongly encouraged to engage other key hospital/health system stakeholders in the vendor selection process.
- While this tool is intended to be useful for all health-system/hospital-based departments of pharmacy, its use will vary based on the institution's size, geographic location, services provided and available resources.
- The ASHP Foundation has attempted to include the assessment questions under the most appropriate category. However, in some cases an assessment question might be applicable to multiple categories.
- While this document is intended to be helpful to hospital/health-system departments of pharmacy in their selection of a sterile products outsourcing organization, it does not purport to establish a standard of care.
- Hospitals/health systems that plan to use this tool as a component of their evaluation of a sterile products outsourcing organization can also use the tool to develop a Request for Proposals (RFP) for these services.
- The ASHP Foundation strongly encourages hospitals/health systems to use this tool along with site visits to ensure a comprehensive review of potential sterile products outsourcing organizations. Items that should be closely evaluated during the site visit are indicated throughout the tool.
- As part of the hospital's/health system's overall planning for selection of a sterile products outsourcing organization, see the ASHP Guidelines on Outsourcing Sterile Compounding Services.
- The term "disqualification" as used in this tool means that the outsourcing contractor should not be considered for the provision of sterile products preparation services.
- This tool is not intended for use in the evaluation of nuclear pharmacies.

The information contained in this self-assessment tool is constantly evolving because of ongoing research and improvements in technology and is subject to the professional judgment and interpretation of the involved health care professionals. The ASHP Research and Education Foundation, the expert panel, and external peer reviewers have made reasonable efforts to ensure the accuracy and appropriateness of the information presented. However, any reader of this information is advised that the ASHP Research and Education Foundation, the expert panel, and the external reviewers are not responsible for the continued currency of the information, for any errors or omissions and/or for any consequences arising from the use of the information in the self-assessment tool in any and all practice settings. Any reader of this document is cautioned that the ASHP Research and Education Foundation makes no representation, guarantee or warranty, express or implied, as to the accuracy and appropriateness of the information contained in this self-assessment tool and will bear no responsibility or liability for the results or consequences of its use.

7272 Wisconsin Avenue
Bethesda, MD 20814
301-664-8612

How to Use this Tool

Step 1. Minimum Requirements for a Vendor

When outsourcing the production of sterile products the first step in vendor evaluation is to see if they meet the minimum requirements. We have developed a group of questions that can be used to qualify a vendor. There is not a score for this section. A vendor simply meets the minimum requirements or they are disqualified. Once a vendor has been qualified we suggest further assessment of the vendor to determine which vendor is the best fit for your hospital or health-system.

Step 2. Vendor Assessment

The questions in this section are designed to help you objectively compare the services offered by potential outsourcing vendors. After answering each question, the Assesment Tool provides a score for the vendor and a table to interpret the score.

Step 3. Vendor Comparison

The vendor scores and score legend provided in the Assessment Summary can be used to compare potential outsourcing vendors.

OUTSOURCING STERILE PRODUCTS PREPARATION
CONTRACTOR ASSESSMENT TOOL

Reset

Step 1: Minimum Requirement Questions

Part 1: Regulatory Compliance

1. Does the outsourcer have a state pharmacy license available where the compounding center resides?

   ○ Yes ○ No

2. Is the outsourcer licensed to ship to my state?

   ○ Yes ○ No ○ N/A

3. If the outsourcer prepares a significant number of non patient-specific preparations (e.g., >5% of the outsourcer's volume), is the outsourcer registered as a drug manufacturer with the FDA, if required?

   ○ Yes ○ No ○ N/A

4. If the outsourcer prepares non patient-specific controlled substance preparations, is the outsourcer registered as a drug manufacturer with the DEA?

   ○ Yes ○ No ○ N/A

5. Are all pharmacists working for the outsourcer licensed in the state in which they are practicing?

   ○ Yes ○ No

6. If required, are all of the outsourcer's pharmacy technicians licensed or registered in the state where they are practicing?

   ○ Yes ○ No ○ N/A

7. Does the outsourcer meet or exceed state required pharmacist-to-pharmacy technician ratios for the state in which the compounding center is located?

   ○ Yes ○ No ○ N/A

8. If an FDA-approved product is commercially available (not on backorder), does the outsourcer compound the same drug formulation using non-sterile powders or other components?

   ○ Yes ○ No

9. When no commercial source exists to prepare admixtures, does the outsourcer use USP grade bulk ingredients obtained from a cGMP compliant supplier? If yes, can the outsourcer provide a certificate of analysis and potency testing of all bulk ingredients used?

○ Yes ○ No ○ N/A

10. Does the outsourcer have the required minimum amount of product liability insurance as outlined by my institution?

○ Yes ○ No

11. Will my institution be covered by this insurance in the event that there is no written contract with the outsourcer?

○ Yes ○ No

Part 2: Quality and Patient Safety Measures

12. Can the outsourcer provide documentation that confirms staff competency (garbing and hand hygiene, aseptic technique and related practices, and cleaning and disinfection procedures) is evaluated prior to compounding of actual drug preparations?

○ Yes ○ No

13. Can the outsourcer provide documentation that confirms that the outsourcer tests aseptic techniques by preparing media fill units per USP chapter <797> standards?

○ Yes ○ No

14. Can the outsourcer provide documentation that confirms that pharmacists and pharmacy technicians are pre-qualified using media fills before compounding of actual drug preparations?

○ Yes ○ No

15. How often are outsourcing staff required to undergo re-qualification using media fills?

○ More than once per year ○ Annually ○ Less than annually or never

16. If a positive media fill occurs, does the outsourcer perform a comprehensive investigation to identify root cause?

○ Yes ○ No

17. If a positive media fill occurs, does the outsourcer institute corrective and preventive action?

Yes No

18. Does the outsourcer provide customers with substantial evidence that supports extended expiration dating for compounded sterile preparations when BUD limits in USP <797> are exceeded?

Yes No

19. Does the outsourcer perform studies to determine extended expiration dates, using evidence-based and validated stability testing procedures, for compounded sterile preparations for which no extended expiration evidence exists?

Yes No

20. Does the outsourcer verify that staff members are complying with gowning, gloving, and glove-tip processes that are consistent with USP chapter <797> standards?

Yes No

21. Does the outsourcer perform routine surface microbiological and fungal environmental monitoring to minimize contamination?

Performs More than Weekly Performs Weekly

Does Not Perform Weekly

22. Does the outsourcer perform comprehensive investigations of out-of-limit findings, as recommended by USP chapter <797>, to determine root cause, followed by corrective and preventative actions?

Exceeds USP <797> Guidelines (Performs more than weekly) Meets USP <797> Guidelines (Performs weekly)

Does not meet USP 797 Guidelines

23. How frequently does the outsourcer perform nonviable and viable particle testing in primary engineering controls (e.g., laminar flow workbench, biological safety cabinet) and room air according to USP chapter <797> standards?

Exceeds USP <797> Guidelines (Performs more than semiannually) Meets USP <797> Guidelines (Performs semiannually)

Does not meet USP 797 Guidelines

24. Does the outsourcer have a policy that requires validation of new or changed facilities, equipment, processes, container types, for sterility, and repeatability?

Yes No

Part 3: Medication Administration Safety Features

25. Does the outsourcer provide readily accessible information regarding status of latex, DEHP and preservatives in the preparations they prepare?

Yes No

Part 4: Service Excellence

26. Does the outsourcer compound products in the containers types (e.g., syringes, minibags, pump-specific cassettes) to meet the needs of my institution?

Yes No

27. Does the outsourcer have business continuity plans in place in the event of a natural or man-made disaster or public health emergency?

Yes No

Minimum Requirement Assessment Results

You must answer all 27 minimum requirement questions before the results of the Minimum Requirement Assessment are displayed.

Step 2. Vendor Assessment

The following questions are designed to help you objectively compare the services offered by potential outsourcing vendors. After answering each question, the Assessment tool provides a score for the vendor and a table to interpret the score.

PART I: REGULATORY COMPLIANCE
(20% of Total Score)

Section One: Current Registration and Licensure

1. What percentage of the outsourcer's pharmacy technician staff are certified by an authoritative board (e.g., Pharmacy Technician Certification Board)?

   ◯ < 50 % ◯ 50-94% ◯ ≥95%

2. Does the outsourcer provide pedigree information that documents that they do not purchase products outside of traditional drug distribution networks or through secondary wholesalers?

   ◯ Yes, all available ◯ Some or no Pedigree Information available

3. If a commercial product component of a preparation is on backorder, can the outsourcer provide a certificate of analysis, potency testing, and proof that all other requirements are met (e.g., higher level clean room) for High Risk Level Compounding?

   ◯ Yes ◯ No ◯ N/A

4. Does the outsourcer meet ASHP guidelines for handling of hazardous agents?

   ◯ Yes ◯ No ◯ N/A

5. Does the outsourcer meet NIOSH guidelines for handling of hazardous agents?

   ◯ Yes ◯ No ◯ N/A

6. Does the outsourcer meet USP chapter <797> guidelines for handling of hazardous agents?

   ◯ Yes ◯ No ◯ N/A

OUTSOURCING STERILE PRODUCTS PREPARATION
CONTRACTOR ASSESSMENT TOOL

Section Two: Availability of Reports and Technical Summaries

7. Has the outsourcer disclosed any disciplinary or punitive action by any regulatory agency.(e.g., FDA warning letter, state board of pharmacy) within the past 36 months?

- Yes, still unresolved
- Yes, resolved
- No

8. Does the outsourcer provide quality control history and quality assurance trend reports on a regular basis and upon request?

- All available
- Some or none available

PART 1 SCORE: Answer all questions to see score.

ASSESSMENT PROGRESS: Part 1 | Part 2 | Part 3 | Part 4

PART 2: QUALITY AND PATIENT SAFETY MEASURES
(50% of Total Score)

Section One: Personnel Competency Through Media Fills

9. Can the outsourcer provide documentation that confirms that sterile media used are certified by the manufacturer to be sterile and guaranteed to promote growth?

- Yes
- No

10. Can the outsourcer provide detailed reports on the incidence of positive media test results and the follow-up retests after corrective action is completed? During ongoing media monitoring, how many times in the last year were positive media fills reported on requalifications?

- Never
- Once
- More than once

Section Two: Availability of Reports and Technical Summaries

11. In assigning expiration and beyond-use dating, does the outsourcer follow evidence-based and validated stability testing procedures to evaluate each preparation's (drug, diluent and device/container) potency at room temperature or refrigerated temperature as applicable?

○ Follows procedures ○ Does not follow procedures

12. In assigning expiration and beyond-use dating, does the outsourcer follow evidence-based and validated stability testing procedures to evaluate each preparation (drug, diluent and device/container), based on a range of extreme temperatures, to ensure stability and determine the impact on the preparation (e.g. evaporation, precipitation, degradation, concentration)?

○ Follows procedures ○ Does not follow procedures

13. In assigning expiration and beyond use dating, does the outsourcer follow evidence-based and validated stability testing procedures to evaluate each preparation (drug, diluent and device/container) for chemical characteristics such as pH, particulate matter, color, sterility (container closure integrity testing)?

○ Follows procedures ○ Does not follow procedures

14. Does the outsourcer provide minimum guaranteed shelf life upon delivery?

○ Yes ○ No

Section Three: Maintenance of Sterility and Environmental Monitoring

Site Visit Question

15. Does the outsourcer document that cleaning methods and agents are effective in preventing contamination of the sterile preparations area?

○ Yes ○ No

Site Visit Question

16. Are sporicidal agents used to sanitize vials and ports to prevent spore growth?

○ Yes ○ No

17. Does the outsourcer have action and alert limits for environmental monitoring?

○ Yes ○ No

18. For systems that require validation, does the outsourcer initiate corrective and preventive actions based on a formal review process?

Yes No

19. Does the outsourcer have a change control process for times when preventive maintenance is completed or equipment or software upgrades are installed?

Yes No

20. Does the outsourcer have documented processes and procedures (including shipping validation studies) to ensure that preparations leaving the site retain their integrity and stability through the shipping cycle?

Yes No

PART 3: MEDICATION ADMINISTRATION SAFETY FEATURES
(20% of Total Score)

Section One: Quality Label

21. Does the outsourcer use drug name differentiation in the form of TALL MAN lettering as defined by an authoritative body for sound-alike and look-alike drugs?

Yes No

22. Does the outsourcer use visual cues on the label to differentiate drug names and drug concentrations within a therapeutic class?

Yes No

23. Does the outsourcer's labeling provide total drug amount and concentration (e.g., mg/mL) to ensure administration of the correct dose?

Yes No

24. Does the outsourcer provide auxiliary cautionary labeling to indicate contraindicated routes of administration?

Yes No

25. Does the outsourcer use ASTM (American Society for Testing and Materials) color coding for anesthesia syringe preparations?

Yes No N/A

26. Does the outsourcer have the capability to provide additional risk cues on anesthesia syringes to differentiate drugs within a therapeutic class and/or concentration?

Yes No N/A

27. Does the outsourcer provide access to information on latex, DEHP and preservative free products 24 hours per day, 7 days per week?

Yes No

28. Does the outsourcer provides machine-readable bar codes on all of its labels?

Yes No

29. Does the outsourcer provide comprehensive bar coding that includes the national drug code (when available) number, lot number, and expiration date?

Yes No

30. Does the outsourcer provide label formats and bar code placement that allow visualization of drug name and concentration when used in the institution's automated infusion pumps or syringe pumps?

Yes No N/A

Section Two: Tamper Evidence

31. Does the outsourcer offer tamper-evident options which may include overwrap, shrink wrap, tamper-evident foil, and/or tamper-evident caps?

Yes No

PART 4: SERVICE EXCELLENCE
(10% of Total Score)

Section One: Product Availability and Breadth of Line

32. Can the outsourcer provide concrete examples of their ability to provide new services to meet the evolving patient care needs of my institution?

Yes No N/A

33. Does the outsourcer compound medications for epidural administration?

Yes No N/A

34. Does the outsourcer compound medications for intrathecal administration?

Yes No N/A

35. Does the outsourcer compound controlled substances?

Yes No N/A

36. Does the outsourcer compound patient controlled analgesia solutions?

Yes No N/A

37. Does the outsourcer compound anesthesia syringes?

Yes No N/A

38. Does the outsourcer compound solutions for continuous nerve blocks?

Yes No N/A

39. Does the outsourcer compound antibiotics?

Yes No N/A

40. Does the outsourcer compound electrolyte solutions?

Yes No N/A

41. Does the outsourcer compound total parenteral nutrition?

Yes No N/A

42. Does the outsourcer compound cardioplegia solutions?

Yes No N/A

43. Does the outsourcer compound solutions for use in the critical care setting?

Yes No N/A

44. Does the outsourcer compound CRRT (Continuous Renal Replacement Therapy) preparations?

Yes No N/A

45. Does the outsourcer compound oxytocin solutions?

Yes No N/A

46. Does the outsourcer compound chemotherapy?

Yes No N/A

47. Does the outsourcer fill elastomeric containers/pumps?

Yes No N/A

48. Does the outsourcer compound medications for use in pediatric patients?

Yes No N/A

Section Two: Ease of Ordering

49. Does the outsourcer provide easy, convenient and reliable web-based ordering?

Yes No

50. Does the outsourcer offer E-222 "CSOS" ordering for controlled substance purchases?

Yes No N/A

51. Does the outsourcer offer a real-time, online reporting tool (e.g., shipment tracking, order history, invoices)?

Yes No

Section Three: Order Turnaround Time

52. Does the outsourcer provide guaranteed timeframes that meet your organization's needs for compounded sterile preparations?

Yes No

53. Does the outsourcer provide same-day delivery?

Yes No

54. Does the outsourcer provide next-day delivery?

Yes No

Section Four: Storage and Space

Site Visit Question

55. Does the outsourcer's current production capacity meet the requirements of the organization?

Yes No

56. Is the outsourcer willing to work with the organization on suggestions for improvement in storage solutions (e.g., customized packaging)?

Yes No

57. Has the outsourcer incorporated green programs (e.g., waste reduction initiatives) into their services?

Yes No

Site Visit Question

58. If the outsourcer prepares compounded sterile products using controlled substances, is the storage area for these secure and is staff identification required prior to entry into the area?

Yes No

Section Six: Service Considerations

59. Does the outsourcer negotiate prices with group purchasing organizations?

Yes No N/A

60. Does the outsourcer have a mechanism to respond to customer service issues or questions 24 hours a day, 7 days a week?

Yes No

61. Does the outsourcer have the clinical expertise in the area of products provided (e.g., TPN)?

Yes No

62. Does the outsourcer have staff members who are knowledgeable in the necessary clinical pharmacy areas to the support the efforts of its customers in driving change within the hospital?

Yes No

63. Does the outsourcer have staff members who are knowledgeable in the necessary clinical pharmacy areas who can ensure that an order received from a hospital is clinically and therapeutically appropriate?

Yes No

64. Can the outsourcer provide consultation services regarding potential compounding efficiencies and practice changes that can result from analysis of compounding patterns?

Yes No

65. Does the outsourcer have a track record for innovation and process evolution as evidenced by customer testimonials?

Yes No

Step 3: Assessment Summary

Sterile Products Outsourcing Tool (SPOT)					
Vendor Qualification*	Number of Questions	Total Raw Score			Total Points
Part 1-4	27				
Vendor Assessment	Number of Questions	Total Raw Points	Available Points	Section Weight	Section Score
Part 1: Regulatory	8	0	30	20%	0
Part 2: Quality and Patient Safety	12	0	23	50%	0
Part 3: Medication Administration Safety Features	11	0	32	20%	0
Part 4: Service Excellence	34	0	61	10%	0
Total	**65**	**0**	**146**	**100%**	**0%**

* A zero in the Total Points section under Vendor Qualification indicates that the vendor is disqualified due to an unacceptable response to one or more minimum requirement questions.

Contractor Assessment Tool Score:

0%

Interpret Your Score:

- **90-100%** Excellent
- **80-89%** Good
- **70-79%** Consider other options
- **≤ 69%** Vendor is disqualified due to an unacceptable response to one or more minimum requirement questions.

FOR IMMEDIATE RELEASE

REF 2011-07

ASHP Foundation

ASHP Foundation News Release

ASHP Foundation Offers Sterile Products Outsourcing Tool
New resource helps pharmacists evaluate proposals for parenteral product preparation services

BETHESDA, Md. (June 29, 2011) — The American Society of Health-System Pharmacists (ASHP) Research and Education Foundation has developed a new web-based tool that helps pharmacists evaluate proposals from external organizations that provide parenteral product preparation services. *Outsourcing Sterile Products Preparation: Contractor Assessment Tool* is an easy-to-complete, portable PDF form developed with support from PharMEDium Services, LLC.

Preparation of sterile parenteral products is a critical component of health-system pharmacy practice. Many hospital pharmacy departments in the United States contract with external organizations for the sterile preparation of parenteral medications, which presents significant safety and quality implications that impact not only pharmacists, but physicians, nurses and patients.

Users will complete a series of questions to evaluate proposals submitted by potential outsourcing contractors. The assessment tool provides departments of pharmacy with guidance for evaluating outsourcer proposals in the following areas:

- Regulatory compliance
- Quality and patient safety measures
- Medication administration safety features
- Service excellence

Weighted scores are associated with each response, and upon completion, the tool will generate a report that provides comparative data for all RFP responses. This report can then be used, in conjunction with site visits, to evaluate proposals in the context of the hospital's or health system's patient care and operational needs.

"As pharmacy leaders, we are directly responsible for the quality of pharmaceutical services and products provided to our patients, including those products and services obtained from outsourcing vendors," says William W. Churchill, M.S., R.Ph., chief of service in Brigham and Women's Hospital's department of pharmacy in Boston, Mass. "It is imperative that pharmacy leaders not make assumptions about quality but rather must proactively assess the ability of outsourcing vendors to provide the high-quality products and services that we demand for our patients. This new assessment tool will provide pharmacy leaders with a comprehensive set of objective criteria that will help them complete a proper vendor assessment and make an informed decision on which vendors with whom they do and do not want to do business. Pharmacy directors across the country must take advantage of the tool and start the vendor assessment process now!"

"The ASHP Foundation has designed an exceptionally useful tool to help pharmacists assure that outsourced sterile compounding services will match the level of quality and patient safety they'd expect in their own practice," said Mike Cohen, R.Ph., M.S., Sc.D., president of the Institute for Safe Medication Practices in Horsham, Pa. "Use of the tool should be a required step in the process of choosing an appropriate vendor."

For More Information
To access the Sterile Products Outsourcing Tool, please visit our website at www.ashpfoundation.org/SterileProductsTool.

About the ASHP Foundation
The ASHP Research and Education Foundation was established in 1968 by the American Society of Health-System Pharmacists as a nonprofit, tax-exempt organization. As the philanthropic arm of ASHP, our vision is that patient outcomes improve because of the leadership and clinical skills of pharmacists, as vital members of the health care team, accountable for safe and effective medication use. Our mission is to improve the health and well-being of patients in health systems through appropriate, safe and effective medication use.

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